

Certificate of quality certificated reference material

Product appellation: Lyophilized long-term cell count standard (SCC1 – SCC5)
Charge / Batch: D00M12Y23

Description of CRM / Product description:

Shock frozen cow milk with Bronopol and Polypropylenglycol.
Samples are only for laboratory usage and not for human consumption!

Packaging:

Glass bottles, sealed with buckler and aluminium cap.
15 mL resuspended sample per packaging unit.

Application:

The materials are suitable for checking accuracy of measurement results in milk analysis.

- Comparison in reference analysis, e. g. microscopic methods.
- Slope/Intercept calibration and adjustment of analytical instruments in routine analysis.

Reference values:

Parameter	Method	Product appellation	Number acc. laboratory	Number of data points	Reference value ¹ ± expanded uncertainty (k=2) ²	
Somatic Cells	Flow Cytometry / microscopy	SCC1	7	42	112.000 ± 36.600	cells /mL
		SCC2	7	45	234.000 ± 45.100	
		SCC3	7	45	374.000 ± 42.000	
		SCC4	7	45	684.000 ± 73.600	
		SCC5	7	45	1.041.000 ± 104.900	

The parameter was analyzed in different accredited laboratories according to ISO/IEC 17025; each laboratory analyzed in multiple determination. In two fluorescence-optical devices used, six results were returned to the reference values of the Golden Standard ERM BD001 of the European Commission.

¹ The reference value corresponds to the arithmetic mean of all statistically checked single values and represents the best estimator with an uncertainty range of 95 %.

² Estimated expanded uncertainty with a coverage factor of k=2, corresponding to a confidence level of about 95 % as defined in Guide to the expression of uncertainty in measurement (GUM) and ISO Guide 35. Uncertainty contributions resulting from the characterization, the uncertainty in two fluorescence-optical devices with regard to the Golden Standard ERM BD001 of the European Commission as well as from the homogeneity and stability test were taken into account.

The metrological traceability is based on the above-named reference method.

Stability:

Short-term stability under extreme transport conditions and long-term stability of the materials were checked with comparable materials. Stability was confirmed.

The material is best used before:

SCC 1 – SCC 5	2028-06
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Reference values and their uncertainties are guaranteed under the precondition that the material is stored, prepared and used as described below.

Homogeneity:

Homogeneity between packaging units was determined according to ISO Guide 35 on the basis of at least 10 samples taken stratified random from the whole batch.

In addition, we will inform you about the results of the homogeneous filling.

Homogeneity between packaging units is satisfactory.

Parameter	Product appellation	Range of dispersion (95 %) ³	
Somatic Cells	SCC1	4.500	cells/mL
	SCC2	19.200	
	SCC3	10.700	
	SCC4	27.100	
	SCC5	28.500	

³ Estimated from twice the standard deviation of the packing units.

Storage:

Samples must be stored in a suitable refrigerator.

Storage temperature:	≤	6 ± 2 °C
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Preparation / Usage:

The samples must be prepared and used according to the “INSTRUCTION FOR PREPARATION OF LYOPHILIZED LONG-TERM CELL COUNT STANDARD”. Each sample has to be reconstituted with **16,10 ± 0,09 g** of sterile water. The instruction is enclosed to each delivery. Manifold measurements and calculation of the mean lead to more reliable results.

Notes:

QSE GmbH guarantees the correctness of the somatic cells only if the instruction of preparation and the use of the unchanged material are observed. The material is, in principle, a homogeneous material, on the basis of which no minimum removal rate is specified. The material is suitable for the usual analysis procedures in the dairy industry. On request, the product description and the safety data sheet are available for further information.

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Nadine Schreiber, QSE GmbH
head of production

This quality certificate was created
electronically and is valid without a signature.